

REMARKS

Reconsideration of this application and reexamination of the claims in view of the amendments and remarks presented herein are respectfully requested. Claims 1, 3-9, 13-23, 35, 37-39, and 41-80 have been cancelled; claims 10, 12, 24, 29-32, and 40 have been amended; and new claims 81-115 have been added. Claims 2, 10-12, 24-34, 36, 40, and 81-115 are pending.

New claims 81-86 find support, for example, in original claims 22 and 23. New claims 87-109 and 112-115 find support, for example, in original claims 2, 3, 10-12, 22-34, 36, 40, 87, 88, and 97. Further support for new claims 113-115 is provided, for example, by Example 6. The recitation of “greater than 80%” in claims 2, 10, 24, 40, 87, 88, 91, and 103 finds support, for example, in paragraphs 066 and 067. New claims 110 and 111 find support, for example, at paragraph 039 of the specification. No new matter enters by amendment.

Restriction Requirement

In the Restriction Requirement mailed August 23, 2004, the Office characterized Group I as “drawn to a method of preventing or treating a disease using a DC-SIGN modulator/blocker that is a derivative of an effector molecule.” In response to the Restriction Requirement, Applicants elected to prosecute Group I. Based on the Office’s discussion at Item 1 of the current Office Action, it appears that the only non-linking claim within Group I is claim 3. Applicants have cancelled claim 3 herein and amended claim 2 to incorporate the subject matter of Group I.

Specifically, claim 3 recited “wherein the DC-SIGN blocker is a blocking derivative of the effector molecule.” In amended claim 2, the language “DC-SIGN

blocker" is replaced by "a molecule that specifically binds to the DC-SIGN receptor . . . wherein the molecule that specifically binds to the DC SIGN receptor is administered in an amount sufficient to inhibit the binding of the effector molecule to the DC-SIGN receptor by greater than 80% to thereby treat the disease of the mammal." This language makes clear that (1) the molecule specifically binds to the DC-SIGN receptor and (2) that binding inhibits the binding of the effector molecule to the DC-SIGN receptor.

Instead of "is a blocking derivative of the effector molecule," as in claim 3, amended claim 2 now recites "wherein the molecule that specifically binds to the DC-SIGN receptor comprises a binding moiety of the effector molecule that specifically binds to the DC-SIGN receptor." As explained at paragraph 056 of the application, "An 'effector molecule' is any molecule that specifically binds to the DC-SIGN receptor present on cells of a mammal . . ." As described at paragraph 065 of the application, "A 'binding moiety' is that portion of a molecule that substantially retains the ability to bind to a second molecule when other portions of the molecule are removed or modified or when the binding moiety is placed into a heterologous context." Thus, "A binding moiety of an effector molecule is that portion of the effector molecule that substantially retains the ability to bind to DC-SIGN when other portions of the molecule are removed or modified or when the binding moiety is placed into a heterologous context."

(Application at paragraph 065.) In this way, the new language of claim 2 expresses that the "molecule that specifically binds to the DC-SIGN receptor" is a derivative of the effector molecule. Thus, amended claim 2 corresponds to Group I. Similarly, claims 10-12, 29, 30, 87-90, 96, 97, and 112-115 correspond to Group I.

Claims 32-34, 36, 40, 99-103, and 110-111 correspond to Group II; claims 81-86 and 104-109 correspond to Group III, and claims 31 and 38 corresponds to Group IV. Claims 24-28 and 91-95 are generic to Groups I-IV. Applicants request that the generic claims be examined at the time that the claims of Group I (2, 10-12, 29, 30, 87-90, 96, 97, and 112-115) are found allowable. Applicants also request that the remaining pending claims, directed to Groups II-IV, be examined once the generic claims are found allowable.

Claim Objections

The Office objected to claims 1, 24, and 39 for failing to spell out the acronyms DC-SIGN, CMV, and HIV, respectively, at their first occurrence. (Office Action at Item 3.) In response, Applicants have spelled out the acronyms DC-SIGN in claim 2, CMV in claim 24, and HIV in claim 40, at their first uses in the amended claim set (claim 39 has been cancelled). Applicants respectfully request withdrawal of the claim objections.

Claim Rejections Under 35 U.S.C. § 112

The Office rejected claims 24-30, 39, 40 and 42 under 35 U.S.C. § 112, first paragraph, for an alleged lack of enablement. (Office Action at Items 4 and 5.) Specifically, though the Office acknowledges that the specification is enabling for the claimed methods as they encompass treating viral infections, the Office contends that the specification does not reasonably provide enablement for preventing such infections. (Office Action at Items 4 and 5.) Applicants submit that this rejection has been rendered moot by the amendment of claims 24-30 and 40 to no longer recite

“preventing”, and by the cancellation of claims 39 and 42. In making this amendment Applicants do not acquiesce to the Office’s position regarding enablement of preventing the recited viral infections. Applicants reserve the right to prosecute claims that recite “preventing” in continuation and/or divisional applications.

The Office rejected claims 1-3, 9-14, 24-30 and 39-42 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. (Office Action at Item 6.) Applicants respectfully traverse.

As amended, claim 2 recites “wherein the molecule that specifically binds to DC-SIGN is administered in an amount sufficient to inhibit the binding of the effector molecule to the DC-SIGN receptor by greater than 80% to thereby treat the disease of the mammal.”¹ Applicants submit that this language, in conjunction with the disclosure at paragraphs 066 and 067 of the specification, makes the metes and bounds of the claims clear. Accordingly, Applicants respectfully request withdrawal of this rejection.

The Office also stated that claim 3 recites “a blocking derivative of the effector molecule,” and alleged that “It is unclear what a derivative of the effector molecule is. How is this blocker derived from the effector molecule?” (Office Action at Item 6.) Applicants have addressed this ground of rejection above, in the section regarding the restriction requirement and the amendment of claim 2. Applicants submit that the amended claim set makes clear how the blocker (a term that does not appear in the

¹ Some of the other independent claims further limit the origin of the effector molecule. For example, in claim 24, the effector molecule is a “CMV virus effector molecule.”

amended claims) is derived from the effector molecule. Accordingly, Applicants respectfully request withdrawal of this rejection.

Claim Rejections Under 35 U.S.C. § 102

The Office rejected claims 1-3, 9-14, 39, 40 and 42 under 35 U.S.C. § 102(a) as allegedly anticipated by Littman *et al.* (WO 01/64752 A2). (Office Action at Item 7.) According to the Office, "Littman *et al.* discloses antibodies (a blocking derivative of the effector molecule) specific for the antigenic fragment of gp120 (envelope subunit protein of HIV and binding moiety of viral effector molecule) that inhibits DC-SIGN on dendritic cells from interacting with gp120. Also disclosed are methods of treating HIV infection by administering antibodies that bind to gp120, thereby inhibiting binding of gp120 to DC-SIGN. (See Littman *et al.*, page 5, pages 5-6, bridging paragraph, and claims 1-4.)" This rejection has been rendered moot as to claims 1, 3, 9, 13, 14, 39, and 42 by cancellation of the claims. Applicants respectfully traverse the rejection as to claims 2, 10-12, and 40, and submit that it should not be applied to the new claims.

To anticipate Applicants' claims, WO 01/64752 A2 must disclose each and every limitation of the claims. See *Verdegaal Bros v. Union Oil Co. of Calif.*, 814 F.2d 628, 631 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found either expressly or inherently in a single prior art reference."); see also M.P.E.P. § 2131. Applicants claims recite methods comprising administering to a mammal a molecule that specifically binds to the DC-SIGN receptor. In contrast, WO 01/64752 A2 discloses administering antibodies that specifically bind the antigenic fragment of gp120. WO 01/64752 A2 does not disclose that these antibodies

specifically bind to the DC-SIGN receptor. For at least this reason, WO 01/64752 A2 does not disclose every element of the pending claims and does not anticipate the claims. Applicants respectfully submit that this rejection can be withdrawn.

The Office rejected claims 1-3, 9-14, 39, 40, and 42 under 35 U.S.C. § 102(b) as allegedly anticipated by Figdor *et al.* (EP 1046651 A1, herein, “Figdor”). (Office Action at Item 8.) According to the Office, “Figdor discloses a method for treating HIV infection in humans comprising administering humanized monoclonal antibodies (modulator/blocker) that bind DC-SIGN on dendritic cells. The binding of DC-SIGN prevents HIV gp120 (binding moiety of viral effector molecule) from interacting with DC-SIGN (page 4, [0040], page 5, [0046] and page 7, [0070]-[0071]).” (Office Action at Item 8.) This rejection has been rendered moot as to claims 1, 3, 9, 13, 14, 39, and 42 by cancellation of the claims. Applicants respectfully traverse the rejection as to claims 2, 10-12, and 40 and submit that it should not be applied to the new claims.

To anticipate Applicants’ claims Figdor must disclose each and every limitation of the claims. Claims 2 and 87 recite “wherein the molecule that specifically binds to the DC-SIGN receptor comprises a binding moiety of the effector molecule that specifically binds to the DC-SIGN receptor.” “A binding moiety of an effector molecule is that portion of the effector molecule that substantially retains the ability to bind to DC-SIGN when other portions of the molecule are removed or modified or when the binding moiety is placed into a heterologous context.” (Application at paragraph 065.) An antibody against DC-SIGN does not contain a binding moiety of an effector molecule that specifically binds to the DC-SIGN receptor. Figdor does not anticipate claims 2 and 87 for this reason.

Claim 10, claims 11 and 12 as they depend from claim 10, claim 88, and claims 89 and 90 as they depend from claim 88, recite “wherein the molecule that specifically binds to the DC-SIGN receptor comprises a binding moiety of the viral effector molecule that specifically binds to the DC-SIGN receptor.” “A binding moiety of an effector molecule is that portion of the effector molecule that substantially retains the ability to bind to DC-SIGN when other portions of the molecule are removed or modified or when the binding moiety is placed into a heterologous context.” (Application at paragraph 065.) An antibody against DC-SIGN does not contain a binding moiety of a viral effector molecule that specifically binds to the DC-SIGN receptor. Figidor does not anticipate claims 10-12 and 88-90 for this reason.

Claims 40 and 103 recite “wherein the molecule that specifically binds to the DC-SIGN receptor comprises a binding moiety of the CMV envelope glycoprotein B that specifically binds to the DC-SIGN receptor.” An antibody against DC-SIGN does not contain a binding moiety of the CMV envelope glycoprotein B that specifically binds to the DC-SIGN receptor. Figidor does not anticipate claims 40 and 103 for this reason.

The remaining claims recite or depend from claims that recite “A method of treating a cytomegalovirus (CMV) infection of a mammal” Figidor does not disclose a method of treating a CMV infection of a mammal. Figidor does not anticipate any of the remaining claims for this reason.

The Office rejected claims 1-3, 9-14, 24-30, and 39-42 under 35 U.S.C. § 102(b) as allegedly anticipated by Gehrz *et al.* (WO 91/05876, herein, “Gehrz”). (Office Action at Item 9.) According to the Office, “Gehrz discloses a method for treating human CMV with a cocktail of monoclonal antibodies, one of which binds to gp55, a subunit of

envelope glycoprotein B (abstract and Example 1)." (Office Action at Item 9.) The Office goes on to state that "Although Gehrz does not mention that the monoclonal antibodies bind to DC-SIGN to interrupt binding between glycoprotein B and DC-SIGN, Gehrz's antibodies are inherently interacting with DC-SIGN. When Gehrz administers the antibody cocktail to an AIDS patient (infected with HIV), the antibody cocktail is inherently acting on DC-SIGN." (Office Action at Item 9.) This rejection has been rendered moot as to claims 1, 3, 9, 13, 14, 39, and 42 by cancellation of the claims. Applicants respectfully traverse the rejection as to claims 2, 10-12, 24-30, and 40 and submit that it should not be applied to the new claims.

To anticipate Applicants' claims Gehrz must disclose each and every limitation of the claims. Applicants' claims recite "administering to the mammal a molecule that specifically binds to the DC-SIGN receptor." In contrast, Gehrz discloses monoclonal antibodies that bind to CMV proteins. The DC-SIGN receptor is not a CMV protein. Gehrz does not disclose molecules that bind to the DC-SIGN receptor or methods of using the molecules. Accordingly, Gehrz does not anticipate Applicants' claims.

Regarding the Office's statement that "Gehrz's antibodies are inherently interacting with DC-SIGN" (Office Action at Item 9), Applicants note that to the extent this may be true, it is only so in as much as Gehrz's antibodies, by binding to CMV proteins, restrict the ability of those proteins to bind to DC-SIGN. Even if this is "inherent interacting," to quote the Office, it is most certainly different than and distinct from a method of inhibiting the binding of CMV to DC-SIGN with use of a "molecule that specifically binds to the DC-SIGN receptor," as recited by Applicants claims.

Gehrz does not disclose every element of Applicants' claims and does not anticipate Applicants' claims. Withdrawal of this rejection is respectfully requested.

Double Patenting

The Office provisionally rejected claims 1, 2, 9-14, 39, 40, and 42 under 35 U.S.C. § 101 as claiming the same invention as that of claims 1, 2, 9-14, 38, 39, and 41 of copending Application No. 10/700,491. This rejection has been rendered moot by cancellation of claims 1, 2, 9-14, 38, 39, and 41 of copending Application No. 10/700,491. None of the pending claims claim the same invention as any claim in Application No. 10/700,491. Accordingly, this rejection can be withdrawn.

Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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